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09/785,793	02/16/2	2001	Bertrand Seraphin	11621-004-999	5538
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)					
	09/785,793	SERAPHIN ET AL.					
Office Action Summary	Examiner	Art Unit					
·	Ja-Na Hines	1645					
The MAILING DATE of this communication app	pears on the cover sheet with the c	orrespondence address					
Period for Reply							
A SHORTENED STATUTORY PERIOD FOR REPL' WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.1 after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period versilize to reply within the set or extended period for reply will, by statute Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be timusely and will expire SIX (6) MONTHS from a cause the application to become ABANDONE	N. nely filed the mailing date of this communication. D (35 U.S.C. § 133).					
Status	,						
1) Responsive to communication(s) filed on 18 O	ctober 2006.						
2a)⊠ This action is FINAL . 2b)☐ This	This action is FINAL . 2b) ☐ This action is non-final.						
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is							
closed in accordance with the practice under E	x parte Quayle, 1935 C.D. 11, 45	53 O.G. 213.					
Disposition of Claims							
4) Claim(s) 29-54 is/are pending in the application	4)⊠ Claim(s) <u>29-54</u> is/are pending in the application.						
4a) Of the above claim(s) is/are withdrawn from consideration.							
5) Claim(s) is/are allowed.							
6)⊠ Claim(s) <u>29-54</u> is/are rejected.	6)⊠ Claim(s) <u>29-54</u> is/are rejected.						
7) Claim(s) is/are objected to.							
8) Claim(s) are subject to restriction and/o	r election requirement.						
Application Papers							
9) The specification is objected to by the Examine	r.						
10) The drawing(s) filed on is/are: a) □ acce	epted or b) \square objected to by the $\mathfrak l$	Examiner.					
Applicant may not request that any objection to the	drawing(s) be held in abeyance. See	e 37 CFR 1.85(a).					
Replacement drawing sheet(s) including the correct 11) The oath or declaration is objected to by the Ex							
Priority under 35 U.S.C. § 119		•					
12) ☐ Acknowledgment is made of a claim for foreign a) ☐ All b) ☐ Some * c) ☐ None of:	priority under 35 U.S.C. § 119(a)	-(d) or (f).					
1. Certified copies of the priority documents have been received.							
2. Certified copies of the priority documents have been received in Application No							
3. Copies of the certified copies of the priority documents have been received in this National Stage							
application from the International Bureau (PCT Rule 17.2(a)).							
* See the attached detailed Office action for a list	of the certified copies not receive	d.					
Attachment(s)							
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)	4) Interview Summary Paper No(s)/Mail Da						
Notice of Draitsperson's Patent Drawing Review (PTO-946) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 1/17/06.	5) Notice of Informal P 6) Other:						

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DETAILED ACTION

Amendment Entry

1. The amendment filed October 18, 2006 has been entered. It is noted that Applicant has cancelled claims 1-28. It is noted that the amendment of January 17, 2006 has already used claims 28-38. Therefore the new claims from the amendment dated October 18, 2006 should be identified appropriately, i.e., with new claim numbers. However claims 29-54 are under consideration in this office action.

Withdrawal of Rejections

- 2. The following rejections have been withdrawn in view of applicants' amendments and arguments:
- a) The scope of enablement rejection of claims 1-12 under 35 U.S.C. 112, first paragraph;
- b) The written description rejection of claims 1-12 under 35 U.S.C. 112, first paragraph;
- c) The rejection of claims 1-9 and 11-12 under 35 U.S.C. 102(b) as being anticipated by Darzins et al., (WO 96/40943 published December 19, 1996); and
- d) The rejection of claim 10 under 35 U.S.C. 103(a) as being unpatentable over Darzins et al., (WO 96/40943 published December 19, 1996) in view of Zheng et al., (1997).

Response to Arguments

3. Applicant's arguments with respect to claims 1-12 have been considered but are moot in view of the new ground(s) of rejection.

New Grounds of Rejection

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 38 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Neither the specification nor originally presented claims provides support for a method wherein the fusion protein comprises the following components in the order stated, starting from the N- or the C-terminus, (a) one or more IgG binding domains of protein A of *Staphylococcus aureus*; b) Tobacco Etch Virus protease NIA cleavage site; c) one or more calmodulin binding peptides; and (d) said polypeptide of interest.

Applicant did not point to support in the specification for a method wherein the fusion protein comprises the following components in the order stated, starting from the N- or the C-terminus, (a) one or more IgG binding domains of protein A of Staphylococcus aureus; b) Tobacco Etch Virus protease NIA cleavage site; c) one or

more calmodulin binding peptides; and (d) said polypeptide of interest. Moreover, applicant failed to specifically point to the identity or provide structural characteristics of a fusion protein comprises the following components in the order stated, starting from the N- or the C-terminus, (a) one or more IgG binding domains of protein A of Staphylococcus aureus; b) Tobacco Etch Virus protease NIA cleavage site; c) one or more calmodulin binding peptides; and (d) said polypeptide of interest. Thus, there appears to be no teaching of the fusion protein as instantly claimed. Applicant has pointed to paragraphs [0012, 0033, 0044 and 0047], of the instant specification and claims for support of the amendment, however it appears that the sections do not a fusion protein comprises the following components in the order stated, starting from the N- or the C-terminus, (a) one or more IgG binding domains of protein A of Staphylococcus aureus; b) Tobacco Etch Virus protease NIA cleavage site; c) one or more calmodulin binding peptides; and (d) said polypeptide of interest. Therefore, it appears that there is no support in the specification. Therefore, applicants must specifically point to page and line number support for the identity the fusion protein having the recited order as recited by the newly added claim. Therefore, the new claim incorporates new matter and is accordingly rejected.

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Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

- 5. Claims 32, 38 and 41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
- a) Claim 32 recites the limitation "the Tobacco Etch Virus protease" in the claim.

 There is insufficient antecedent basis for this limitation in the claim.
- b) Claim 38 recites the limitation "the N- or the C-terminus" in the claim. There is insufficient antecedent basis for this limitation in the claim.
- c) Claims 41 under 35 U.S.C. 112, second paragraph, is being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is maintained. Claim 41 recites the use of SEPHAROSE TM beads.

A trademark is used to identify a source of goods, and not the goods themselves. Thus, a trademark does not describe the goods associated with the trademark. Furthermore, the use of trademarks is improper since products identified by trademarks are within the sole control of the trademark owner and are subject to change by said owner at their discretion. The very fact that a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, means that the claim does not comply with the requirements of the 35 U.S.C. 112, second paragraph. *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982).

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The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. In fact, the value of a trademark would be lost to the extent that it became descriptive of a product, rather than used as an identification of a source or origin of a product. Thus, the use of a trademark or trade name in a claim to identify or describe a material or product would not only render a claim indefinite, but would also constitute an improper use of the trademark or trade name. If a trademark or trade name appears in a claim and is not intended as a limitation in the claim, the question of why it is in the claim should be addressed. Therefore, the claim scope is uncertain and the use of the trademark constitutes an improper use.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 6. Claims 29-35, 37-43, 45-48 and 52-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Darzins et al., (WO 96/40943 published December 19, 1996) in view of Sassenfeld (1990. Trends Biotechnol. Review. Vol.8(4):88-93).

The claims are drawn to a method for purifying a polypeptide of interest, or a biomolecule complex comprising the polypeptide of interest, said method comprising:

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(a) providing a eukaryotic expression environment such that a fusion protein is expressed trader conditions that allow formation of a complex between the fusion protein and one or more other biomolecules; said fusion protein comprising said polypeptide and at least two different affinity tags; and b) purifying said polypeptide, or any said complex that forms, by performing a combination of at least two different affinity purification steps, each comprising binding the fusion protein, or a truncated fusion protein wherein one of the affinity tags is cleaved off, via one affinity tag to a support material capable of selectively binding one of the affinity tags, and separating the fusion protein or the truncated fusion protein or the polypeptide from the support material after Substances not bound to the support material have been removed, wherein any of said one or more other biomolecules which are bound to said polypeptide in any said complex remain associated with said polypeptide during said step (b), thereby purifying said polypeptide of interest or biomolecule complex comprising said polypeptide of interest.

Darzins et al., teach the construction and use of expression vectors comprising a method for expressing proteins whereby the desired protein product is purified (page 8-9, lines 28-2). Darzins et al., teach the construction and use of host/vector systems that uses protein configurations fused to a combination of polyhistidine tags and protein A IgG binding domains of Staphylococcus, Factor Xa or Tobacco Etch Virus (TEV) protease cleavage sites (page 9, lines 10-14). Darzins et al., teach the construction of fusion proteins, including small DNA fragments containing the recognition sequences that can be placed between the DNA sequences that encode the amino and carboxy

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terminal sorting signal whereby this multiple cloning site will facilitate the insertion of protein coding sequences and upon expression will generate in-frame proteins fusions (page 13, lines 5-11). Darzins et al., teach regulatory sequences controlling gene expression and the use of plasmids which replicate a low copy numbers (page 16, lines 19-30).

Darzins et al., teach the recombinant proteins are purified after cleavage with a specific protease (page 9, lines 16-19). Darzins et al., teach cleavage sites for various proteolytic enzymes being engineered into the expression vectors so that the cleavage sites resides in multiple locations of the peptide (page 14, lines 13-16). Darzins et al., teach the TEV NIA protease which cleaves at a specific consensus cleavage sites (page 14, lines 29-16). Darzins et al., teach following protease treatment the released protein being purified in a variety of ways, including ultrafiltration, centrifugation, molecular-exclusion chromatography, isolelectric precipitation, fractionation, electrophoretic separation, ion-exchange chromatography, affinity chromatography and the like (page 15, lines 17-22). Affinity chromatography is well known in the art of purification by means of using affinity for another substance immobilized on a solid support;

Darzins et al., teach the affinity tags being engineered at either the amino or carboxy terminal regions of the fusion protein (page 16, lines 23-25). Useful affinity tags include polyhistidine tags, IgG binding domain of protein A and glutathione S-transferase (page 15, lines 24-27). Moreover, the affinity tags can be easily removed by incorporating a protease cleavage sites (pages 15-16, lines 30-2). Example 2 teaches

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expression of recombinant genes whereby the recombinant fusion proteins are detected (page 21, lines 5-9). Example 3 teaches purification of recombinant proteins whereby the fusion proteins containing polyhistidine residues can be further purified by passing the supernatant over a resin matrix, an agarose column and further eluting the proteins from an immuno-affinity column (pages 21-22, lines 26-4). However Darzins et al., do not teach the use of eukaryotic expression environment.

Sassenfeld teaches a method for purifying a polypeptide of interest or a biomolecule complex comprising the polypeptide of interest comprise providing a eukaryotic expression environment such that a fusion protein is expressed under conditions that allow formation of a complex between the fusion protein and one or more other biomolecules (page 88, col.1). Sassenfeld teaches the microorganisms commonly used as host as *E.coli* and *Saccharomyces cerevisiae* (page 88, col.1). Sassenfeld teaches secretion of fusion proteins increases the likehood of having a soluble, functional fusion protein (page 88, col.2). Sassenfeld teaches the best techniques for fusion protein having tags where intracellular accumulation of fusion proteins aides in separation and purification (page 88, col.2). Table 2 identifies purification methods including their application to yeast, secreted proteins and/or intracellularly accumulated proteins (page 92). Sassenfeld teaches numerous examples of cloned genes specifically modified to facilitate protein purification wherein the expression of gene fusions results in a fusion protein consisting of the desired protein and purification tags or affinity tags (page 88, col.1). Sassenfeld teaches

purification tags have been used to facilitate affinity, ion-exchange and other separation techniques (page 88, col.1).

Therefore it would have been prima facie obvious at the time of applicants' invention to apply Sassenfeld's eukaryotic yeast expression system to Darzins et al., method for purifying a polypeptide of interest, or a biomolecule complex comprising the polypeptide of interest, in order to provide the best purification tags for intracellularly accumulated fusion proteins. One of ordinary skill in the art would have a reasonable expectation of success by exchanging the expression systems because are both the E.coli of Darzins et al., and the yeast of Sassenfeld are microorganisms commonly used as host of fusion proteins having affinity tags. Furthermore, no more than routine skill would have been required to exchange the expression system of Darzins et al., for the commercially available and functionally equivalent eukaryotic expression system of Sassenfeld since Sassenfeld teaches the purification of fusion proteins in yeast systems when using Protein A IgG-Sepharose tags or glutathione-agarose matrixes. Finally it would have been prima facie obvious to combine the invention of Darzins et al., and Sassenfeld to advantageously achieve by known methods with no change in their respective functions the combination of the prior art references which would yield predictable results to one of ordinary skill in the art at the time of the invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 7. Claim 36 is are rejected under 35 U.S.C. 103(a) as being unpatentable over Darzins et al., (WO 96/40943 published December 19, 1996) and Zheng et al., (1997. Gene. Vol.(186)1: 55-60) further in view of Sassenfeld (1990. Trends Biotechnology. Review. Vol.8(4):88-93).

The claim is drawn to a method for purifying a polypeptide of interest, or a biomolecule complex comprising the polypeptide of interest, said method comprising:

(a) providing a eukaryotic expression environment such that a fusion protein is expressed trader conditions that allow formation of a complex between the fusion protein and one or more other biomolecules; said fusion protein comprising said polypeptide and at least two different affinity tags; and b) purifying said polypeptide, or any said complex that forms, by performing a combination of at least two different affinity purification steps, each comprising binding the fusion protein, or a truncated fusion protein wherein one of the affinity tags is cleaved off, via one affinity tag to a support material capable of selectively binding one of the affinity tags, and separating the fusion protein or the truncated fusion protein or the polypeptide from the support material after substances not bound to the support material have been removed,

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wherein any of said one or more other biomolecules which are bound to said polypeptide in any said complex remain associated with said polypeptide during said step (b), thereby purifying said polypeptide of interest or biomolecule complex comprising said polypeptide of interest wherein at least one of the at least two affinity tags consist of one or more calmodulin binding peptides.

Darzins et al., and Sassenfeld have been discussed above, however neither teaches an affinity tag consisting of at least one calmodulin binding peptide.

Zheng et al., teach expression vectors for protein production, one-step purification and direct labeling of calmodulin-binding peptide (CBP) fusion proteins. CBP proteins can be used in calmodulin affinity chromatography methods (abstract). Zheng et al., teach the CBP tag is small and less likely to affect the biological function of the recombinant fusion protein of interest (page 56, para 1). Zheng et al., teach the CBP tag can be effectively removed by cleavage with thrombin (page 56, para. 2). Zheng et al., teach a common strategy employed to facilitate the purification of recombinant proteins is to fuse the proteins of interest to another peptide or protein, i.e., affinity tags which have specific ligand and hence rapidly and efficiently purify the protein (page 55, para. 2). Other popular affinity tags include polyhistidine tags, protein A, and epitopes for different antibodies (pages 55-56, para. 2).

Therefore it would have been prima facie obvious at the time of applicants' invention to apply Sassenfeld's eukaryotic yeast expression system to Darzins et al., and Zheng et al., method for purifying a polypeptide of interest, or a biomolecule complex comprising the polypeptide of interest, in order to provide the best purification

tags for intracellularly accumulated fusion proteins wherein Zheng et al., modifies the method of purification to further include calmodulin binding protein (CBP) affinity tags which are expressed with recombinant fusion proteins, used in affinity chromatography assays and easily cleaved from fusion proteins. One of ordinary skill in the art would have a reasonable expectation of success by incorporating the CBP affinity tag used in the method for purifying biomolecules and/or protein complexes as taught by Darzins et al., for the affinity tag of Zheng et al., because Zheng et al., teach that CBP tag is small and less likely to affect the biological function of the recombinant fusion protein of interest. Furthermore, exchanging the *E.coli* expression system of Darzins et al., and Zheng et al, for the yeast of Sassenfeld would have a reasonable expectation of success since Sassenfeld teaches the purification of fusion proteins in yeast systems when using Protein A IgG-Sepharose tags, Beta-gal and glutathione-agarose affinity tags. Moreover, one of ordinary skill in the art would have a reasonable expectation of success in simply exchanging an alternative and functionally equivalent affinity tag since Zheng et al, teach that such tags are known to be useful in the art of affinity purification and that such tags function to aid in the purification process.

8. Claim 49 is are rejected under 35 U.S.C. 103(a) as being unpatentable over Darzins et al., (WO 96/40943 published December 19, 1996) and Sassenfeld (1990. Trends Biotechnol. Review. Vol.8(4):88-93) further in view of Sambrook et al. (1989, 2nd Edition, Introduction of Recombinant Vectors into Mammalian Cells, pp. 16.30 to

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16.72, In: Molecular Cloning--A Laboratory Manual, Cold Spring Harbor Laboratory Press).

The claim is drawn to a method for purifying a polypeptide of interest, or a biomolecule complex comprising the polypeptide of interest, said method comprising: (a) providing a eukaryotic expression environment that is a mammalian cell, such that a fusion protein is expressed trader conditions that allow formation of a complex between the fusion protein and one or more other biomolecules; said fusion protein comprising said polypeptide and at least two different affinity tags; and b) purifying said polypeptide, or any said complex that forms, by performing a combination of at least two different affinity purification steps, each comprising binding the fusion protein, or a truncated fusion protein wherein one of the affinity tags is cleaved off, via one affinity tag to a support material capable of selectively binding one of the affinity tags, and separating the fusion protein or the truncated fusion protein or the polypeptide from the support material after substances not bound to the support material have been removed, wherein any of said one or more other biomolecules which are bound to said polypeptide in any said complex remain associated with said polypeptide during said step (b), thereby purifying said polypeptide of interest or biomolecule complex comprising said polypeptide of interest.

Darzins et al., and Sassenfeld have been discussed above, however neither teach a mammalian cell eukaryotic expression system.

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Sambrook et al., teach protocols for the transfection of nucleotide sequences into different cell types such as insect cells, yeast cells, and mammalian cells were standard in molecular biology laboratories at that time. Sambrook et al., teach an introduction of recombinant vectors into mammalian cells, and provides protocols for transfection of DNA into mammalian cells. Sambrook et al., teach transfection of nucleotide sequences into cells was also a very well established, routine technique.

Therefore it would have been prima facie obvious at the time of applicants' invention to apply Sambrook et al., mammalian cells to Sassenfeld's eukaryotic yeast expression system with Darzins et al., method for purifying a polypeptide of interest, or a biomolecule complex comprising the polypeptide of interest, using well established mammalian cell lines as the eukaryotic expression system. One of ordinary skill in the art would have a reasonable expectation of success by including a mammalian expression system of Sambrook et al., because transfection of nucleotide sequences into different cell types such as yeast cells and mammalian cells was standard in molecular biology laboratories Sassenfeld already teach the use of eukaryotic expression system were commonly used as host of fusion proteins having affinity tags. Furthermore, no more than routine skill would have been required to exchange the expression system of Darzins et al., for the commercially available and functionally equivalent eukaryotic expression system of Sassenfeld and Sambrook et al., since Sambrook et al., teach transfection of nucleotide sequences into cells was also a very well established, routine technique. Finally it would have been prima facie obvious to combine the invention of Darzins et al., Sassenfeld and Sambrook et al, to

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advantageously achieve by known methods with no change in their respective functions the combination of the prior art references which would yield predictable results to one of ordinary skill in the art at the time of the invention.

9. Claim 50 is are rejected under 35 U.S.C. 103(a) as being unpatentable over Darzins et al., (WO 96/40943 published December 19, 1996) and Sassenfeld (1990. Trends Biotechnol. Review. Vol.8(4):88-93) further in view of King et al., (1997. Science 277:973-974).

The claim is drawn to a method for purifying a polypeptide of interest, or a biomolecule complex comprising the polypeptide of interest, said method comprising:

(a) providing a eukaryotic expression environment that is a cell-free system, such that a fusion protein is expressed trader conditions that allow formation of a complex between the fusion protein and one or more other biomolecules; said fusion protein comprising said polypeptide and at least two different affinity tags; and b) purifying said polypeptide, or any said complex that forms, by performing a combination of at least two different affinity purification steps, each comprising binding the fusion protein, or a truncated fusion protein wherein one of the affinity tags is cleaved off, via one affinity tag to a support material capable of selectively binding one of the affinity tags, and separating the fusion protein or the truncated fusion protein or the polypeptide from the support material after substances not bound to the support material have been removed, wherein any of said one or more other biomolecules which are bound to said

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polypeptide in any said complex remain associated with said polypeptide during said step (b), thereby purifying said polypeptide of interest or biomolecule complex comprising said polypeptide of interest.

Darzins et al., and Sassenfeld have been discussed above, however neither teach a cell free eukaryotic expression system.

King et al., teach the use of a cell free system to achieve a eukaryotic expression environment. King et al., teach that cell free expression systems substantially expand the range of biochemical assays (page 973, col.1). King et al., teach the use of cell-based expression strategies using mammalian cell lines (page 973, col.1).

Therefore it would have been prima facie obvious at the time of applicants' invention to apply King et al., cell free system to Sassenfeld's eukaryotic yeast expression system with Darzins et al., method for purifying a polypeptide of interest, or a biomolecule complex comprising the polypeptide of interest, using well established mammalian cell lines as the eukaryotic expression system. One of ordinary skill in the art would have a reasonable expectation of success by including a cell free expression system of King et al., because cell free expression systems substantially expand the range of biochemical assays and Sassenfeld already teach the use of eukaryotic expression system were commonly used as host of fusion proteins having affinity tags. Furthermore, no more than routine skill would have been required to exchange the expression system of Darzins et al., for the commercially available and functionally equivalent cell free eukaryotic expression system of King et al., and Sassenfeld is a

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very well established, routine technique. Finally it would have been prima facie obvious to combine the invention of Darzins et al., Sassenfeld and King et al, to advantageously achieve by known methods with no change in their respective functions the combination of the prior art references which would yield predictable results to one of ordinary skill in the art at the time of the invention.

Conclusion

- 10. No claims allowed.
- 11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached Monday thru Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Shanon Foley, can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines January 29, 2008

MARK NAVARRO PRIMARY EXAMINER